REMARKS

1. Substitute Specification. - Applicant is tendering herewith a substitute specification under 37 CFR 1.125, and Applicant makes the affirmative statement that the Applicant believes that the specification contains no new matter. A marked up version of the substitute specification showing all of the changes, including the matter being added to and the matter being deleted from the specification of record, is being submitted herewith, as well.

Applicant believes that the substitute specification addresses all of the objections that have been raised by the Examiner to the specification, as originally filed.

In addition, Applicant is tendering herewith revised drawing figures to meet the objections to the drawings that were raised by the Examiner in the Office Action mailed November 7, 2001. In this regard, the Applicant is tendering a redline version of the new proposed drawing figures as well as a clean copy thereof. Applicant believes that the proposed drawing corrections meet all of the objections to the drawings raised by the Examiner, as previously mentioned.

2. Claim rejections. - Claims 10-12 have been rejected under 35 USC §112, second paragraph, but as the Examiner will note, claims 9-12 have been cancelled and therefore this ground for rejecting the claims has been rendered moot.

Claims 9-12 had also been rejected under 35 USC §102(b) as being anticipated by Taylor, et al. For the reasons that follow, Applicant traverses the application of Taylor, et al. to proposed claims 13-24.

Most of the prior art with intercalated heads ~~pins~~ are intended only for internal fixation, in which after utilizing the outer portion of rod for driving the device, the part beyond the head is

nipped off to leave the rest of it imbedded in bone. Examples of these are Austin Moore pins and Knowles pins, which were mostly used in the hip region.

Other such devices were mostly used in the spine for fixation of plates to that structure. An example is the Steffi screw used along with the plate of that name. The intercalated head was utilized for seating the plate on it after the screws were driven into the vertebra, after which a nut was added to secure the plate to the screw, and excess nibbled off. None of these were intended for participation in external fixator systems.

The device of Taylor et al. has the claim of capability as a lag screw while simultaneously participating in an external fixator.

The device of Taylor et al. has a variety of engagement means or heads that have a flat bottom or base for contact with, or engagement with, the bone surface of a fragment. Thus, the intercalated engagement means of theirs all have an engagement plane, which is at right angles to the rod axis.

This presupposes that the rod will be driven at right angles to the outer surface of bone, because at any other angle the engagement means will stand on edge, with only a small part of the circumference loading stress on a very small area of bone. This will lead to damage by micro fracture, necrosis, and an early loosening.

A fracture always occurs at an angle to the outer bone surface, and travels across bone to exit at the other side, at an angle to that side.

It is a basic mechanical concept, that for maximum compressive torque to be generated by a lag screw, that screw must cross the fracture plane at as nearly a right angle as possible. At any other angle, the screw may even make the fracture surfaces to slide, instead of compressing them.

A lag screw crossing the fracture plane at right angles can never be at right angles to the outer bone surface, which will result in the flat based engagement means of Taylor et al. always standing on edge.

A rare exception when a lag screw cannot cross fracture plane at right angles is when more than two fragments are being compressed by one screw, across more than one fracture plane. Even then one cannot expect the screw to subtend a 90 degrees angle to the surface, and the screw head of Taylor et al. will land on edge.

In the prior art of Taylor et al., there is no conceivable possibility of even a washer of any description, to remedy the defect of head standing on edge.

Such a device of prior art therefore has no practical use in daily fracture management. Taylor et al. have patented engagement means with cone shaped, button shaped, Gemini capsule shaped tops of heads, but the importance of the most relevant basal plane which engages the bone surface has been lost sight of, with consistently incongruent relationship at that interface during actual use.

On the other hand Taylor et al. claim only a device which is a lag screw participating in an external fixator construct.

There is no mention of an improved basic external fixator half pin implant, which is meant for gripping the main fragments, and which is mostly inserted at right angles to the bone surface for maximum efficiency and strength. It is supposed to resist over an adequate period, the significant loosening forces of gravity and muscle contraction. The problem has always been of implant loosening in bone, at the interface between the drill hole and the rod.

There is also the risk of iatrogenic fracture occurring at the defect left after implant extraction, particularly when the hole gets wider due to loosening and infection.

There is prior art of Schanz screws with hydroxyapatite coating, but no change in the basic design of an implant which will make it function more effectively and durably. While a lag screw serves well to compress fracture surfaces, it offers little resistance to other forces. It always needs a neutralization device like a plate or an external construct to protect it. The external fixator required for neutralizing such disruptice forces needs improvement in durability. Lag screw alone does not last.

For all of these foregoing reasons, Applicant respectfully requests entry of the substitute specification tendered herewith, the entry of new claims 13-24, and the allowance of new claims 13-24 over all the prior art of record.

Respectfully submitted,

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CROSS-REFERENCE TO RELATED APPLICATIONS

" Not Applicable"

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

" Not Applicable "

REFERENCE TO A MICROFICHE APPENDIX

" Not Applicable "

New matter

BACKGROUND OF THE INVENTION

This relates to the field of Orthopedics and Trauma, human, or veterinary. It may also have applications in plant biology and non-living mechanical materials.

Bone is living tissue. Bone fragments and surfaces can unite by biological activity over a length of time, given proper conditions to favor it. During this biological process of healing, the fragments have to be held together continuously by various means, to achieve a finally acceptable shape and length of the bone without deformity ,and of sufficient strength to restore function to the part.

The biological process is favored by the following measures.

1. Immobilization of the fragments or surfaces attempting union.

2. Compression of the surfaces to increase the rigidity of immobilization, and also promoting the biological process of direct union without excessive callus formation.

3. To relieve stress and recurrent injury to the soft-tissues and neuro-circulatory mechanisms by the immobilization.

4. Immobilizing only the healing parts, and to encourage movement and activity of un-injured parts.

This has been attempted by the following methods.

A. Continuous traction.

B. External casts of Plaster of Paris, other casting material and braces.

C. Internal fixation.

D. External fixation.

E. Combined methods of fixation.

[F. This refers to the properties of the claimed invention.]

A. Continuous traction:

This can restore the length of the limb, and further measures can correct deformities like rotation and angulation to some extent.

The following problems of this method seldom make it the preferred treatment.

1. It is difficult to maintain the traction force continuously even with very frequent attention.

2. Patient cooperation is difficult to achieve.

3. Due to intermittent loss of traction force, mal-union may occur. Distraction and movement of fragments may cause delay or failure of union.

4. Circulatory problems can occur in the distal limb.

5. Wounds in the traction surface will not allow such a treatment.

B. External casts of Plaster of Paris, other casting material and braces.

The following problems are associated with them.

1. The immobilization is not rigid enough when it is critically essential.

2. Encircling of the part causes sweating and discomfort in hot climates.

3. Pressure sores can occur at pressure points, or due to insertion of hard objects by patient for scratching. Bugs can get in.

4. Swelling of part within the cast can cause tightness and loss of circulation.

5. Loosening of cast occurs due to loss of swelling of part, or due to moisture reducing the thickness of the padding, resulting in loss of reduction.

6. There is no access to any wounds inside which may need attention, except by cutting out windows or leaving the cast incomplete, which may jeopardize the immobilization, and fracture reduction.

7. Uninvolved parts also get immobilized, a setback to recovery.

Due to these factors it can suffice only when rigid immobilization is not critically important, and usually in the absence of complicating factors of wounds and circulation.

C. Internal fixation :-

This may be applied along the side of a bone in the form of a plate and screws of the preferred design. It allows accurate reduction when this is most desirable, a bone graft can be added, and lag screws may be added when feasible, for inter-fragmentary compression. Sliding devices can be added to passively close any gaps arising later.

Disadvantages are as under.

1. Large exposures are required with relatively greater damage to the soft-tissues and bone circulation. Meticulous technique may minimize this, yet exposure is larger.

2. Compression once applied at operation, wears off within hours depending on the quality of bone. There is no possibility of renewing this compression once the wound is closed over the device. It is not acceptable to re-anaesthetize and re-expose the device

repeatedly to re- tighten the screws.

3. Newer minimally invasive methods are performed through smaller incisions but in order to place the plate directly on bone, the periostium and muscles have to be stripped blindly. Even so, the plate is always unavoidably placed over some soft-tissues which melt away by the pressure and loosen the plate within hours. Loss of torque of screws is unfavorable to bone biology.

4. Plates are seldom favored in compound fractures.

5. Fracture haematoma gets dispersed.

Internal fixation may be applied inside the medullary canal of bone in the form of nails, pins and wires.

In closed nailings the fracture haematoma is preserved.

The disadvantages are as under.

1. It is generally not applicable to children, due to growth plates at the ends of bones.

2. It invades and occupies the bone from end to end, with the possibility of spreading infection.

3. It is not stable to rotational forces, and interlocking methods are not available for all situations.

4. In open nailing, the fracture haematoma gets dispersed.

D. External fixation:

This is most ideally suited for open injuries of bone. The commonly used basic bone implant for the external fixator is the Schanz screw which can be inserted at a safe

distance from the open wounds and fracture ends.

1. Access to the wounds for frequent attention is easy.

2. There is no aggravation of injury to bone or soft-tissue.

3. Safe corridor entries of screws prevent injury to neuro-vascular structures.

4. In transverse fracture patterns, some compression can be applied along the axis of the bone.

The following limitations remain:

1. The basic implant e.g. the Schanz screw has a tendency to loosen in bone, leading to instability, and tendency to infection. Radial [stressing] preloading of the implant in bone improves the stability, by the technique of inserting a larger diameter screw in a suitably smaller diameter drill-hole.

2. The preload is only in one mode, viz. Radial.

3. After loosening, there is no way of regaining any degree of stability in the same position, before the onset of infection. If the loose screw had been initially placed in the ideal site, then any next site for re-positioning the screw will be less than ideal.

4. There is no lag screw effect of a Schanz screw, to exert inter-fragmentary compression. Inter-fragment compression greatly enhances the stability, as well as the biological process of union. Fragments can at the most be splinted across, but not drawn together and compressed as in the lag-screw mode, by the conventional Schanz screw.

E. Combined methods of fixation:

When any one method is inadequate to neutralize all the forces of muscular pull and gravity, another method is added onto the first. For example, in " mini- internal fixation"

methods; one or two lag screws used to hold together some fragments, are supplemented by an external fixator construct, or by traction.

Even with such a supplementation, the lag screws can fail, because by the blind stab-hole technique, there is always some interposition of soft-tissue between the screw-head and the bone surface. This soft tissue quickly undergoes pressure necrosis to loosen the compression by loss of torque. The only residual control then is the external fixator, which may not be adequate for joint fragments. The compression once lost cannot be regained.

[E. The claimed invention:] SUMMARY OF THE INVENTION:

This invention aims to preserve and augment the function of the primary bone implant of the external fixator. This is by a design, which adds the effect of an axial preload on the thread in the bone, to the older technique of radially preloading the implant. This has an additional effect on the stability and durability of the screw. The third element of stability is the surface preload of the screw-head on the bone surface. This is independent of the function of the head co acting in exerting axial preload torque on the thread within the bone. These stabilizing qualities are also renewable, because the screw can be again tightened after the first insertion.

Further, there is the introduction of the "lag-screw" function in the same basic implant of external fixator which is [a totally new concept.] in an improved and versatile form, applicable to all situations which arise in fracture care.

There is also the capability of renewed and prolonged inter-fragmentary compression by means of subsequent turning of the screw from outside, which is a new and major advantage to the biology of bone healing.

The major drawback of the conventional [Schanz] screw [of] loosening is corrected to a significant extent, by this triple pre-load mechanism.

All positive features of the older implants are retained.

This device can be used to supplement minimally invasive plate oesteosysthesis with double advantage. The screw torque can be renewed to keep the plate firmly seated on bone. The same screws form a construct outside and prevent failure of implanted plate.

[BRIEF SUMMARY OF THE INVENTION]

[The general idea and the objective of the claimed invention is to overcome some shortcomings of older methods, and to make it more versatile.]

The claimed invention combines the beneficial aspects of internal as well as external fixation. [The older Schanz screw never had any lag-screw function. Even when used across any fracture line, it would merely splint the fracture but could never compress the fragments. Thus the older screw was mainly for gripping the main fragments for participation in the construct. Lag screw mode was entirely a function of the internally fixed screw, and not the Schanz screw.]

[As a member basic implant of the external fixator class, it has multiple stabilizing factors; beyond the present designs; radial preload, axial preload on thread, and surface preload of head on the bone surface. It is designed for increased primary stability and durability and is capable of being re-tightened in the same site, to preserve stability.]

It has no novel disadvantages of any kind whatsoever,[compared to the available

fixator screw implants,] and permits wound access, is applied through minimal incisions, does not damage soft-tissue as in the open reduction and internal fixation methods, does not invade the medullary canal length-wise, and is applicable to children.

[As a member of the internal fixation class of implants It not only holds but compresses the fragments in the lag- screw mode, and also overcomes the problem of invariable loosening soon after first application. Due to its projection outside the skin, it can be re-tightened as required to renew the compression torque, and simultaneously participate in the external construct to augment stability.]

[BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS]

[Drawing 1. It shows the essential features of the invention, which is a rod-like implant with the following components.]

[a. The tip: This is meant for implantation, and may be self-tapping or not. The device in the drawing is cannulated, to permit a guide-wire technique. However, it may be solid in other samples of the device.]

[b. The thread: The drawing shows a partly threaded device, which is intended for use as a lag screw. When intended as a basic implant, or when not intended for compression, the thread extends to the screw- head.]

[c. The smooth shaft of screw section: This is absent in a fully threaded device. The distance between the partial thread and the head is variable to suit the length of the sliding drill-hole.]

[d. The screw head: This is may be shaped hemispherical like the conventional screw – head, discoid, reverse conical, spherical or any other shape so

long as it can rest on the bone surface and be driven tight against it. It may be integrated]

[into the implant body or may be loosely or separately fitted.]

[e. The external drive-shaft:- This extends from the screw- head to the exterior end of the device, and may be of any suitable diameter.]

[f. The grip:- This outer end of the device may be identical with the rod. It may be milled, or flattened to an isosceles triangle for gripping, or a quick-coupling type.
All the dimensions are variable; the diameters of the canulation, the outer thread, the core, the screw-head, the external rod; as also the lengths of the thread, the tip to head distance, and the overall length.]

[Drawing 2.]

[A. This shows the conventional radial preload, by driving a screw into a smaller diameter drill-hole. The view is a cross- section.]

[B. This shows the axial preload on the thread along the axis of the claimed invention, upon the thread in the bone. The implant is axially tensioned. There is radial preload also.]

[C. This shows the surface preload of the screw- head upon the surface of the bone, independent of the axial preload. The fixed flat under – surface is of a limited contact type and used at right angles to bone surface. At any other angle, the under surface is spherical, a washer may be added on a thin cortex. There is also radial preload.]

[Drawing 3. This shows a common variety of hip fracture, treated by internal fixation with a frequently used two- piece device. At the end of fixation, compression is applied between the fracture surfaces, with another smaller fine threaded screw, which

draws the hip-screw into the plate barrel. After the wound is closed over the device, the compression wears off. Any subsequent gap due to bone resorption may get closed by] [sliding of the screw within the barrel. If this passive movement fails to occur, the persistent gap causes failure of union and implant.]

[Drawing 4. The same fracture is treated with an external fixator. The fragments are splinted over the upper two Schanz screws, but no active compression is present. Passive sliding cannot occur, unless the screws are loose in the clamps, making the construct unstable. The lower two screws are the basic implants of the fixator, which can exert preload only in the radial direction, if driven in suitably smaller drill-holes. There is no element in the design for the addition of other preload factors, or for renewability of preloads. Axial preload is not renewable.]

[Drawing 5. The claimed invention is used to create an external fixation construct. The upper two screws actively compress the fracture surfaces by the lag-screw effect. The same screws simultaneously participate in the external construct. Any subsequent loosening can be overcome by re-tightening the lag-screws to regain the compression.]

[The lower two screws are the basic implants for completion of the construct. In addition to a radial preload by technique, the head exerts surface preload on the bone by implant design, adding to the lateral stability. In addition, there is an axial preload along the screw thread on tightening the screw. The latter two effects are incorporated in the design of the invention, and are renewable by re - tightening from without. Axial preload is not renewable but it is protected by the two newer forces.]

[Drawing 6. The claimed device plays an invaluable role in the management of an intra-articular fracture. The articular fragments are not only splinted but actively] [compressed by the claimed invention. This compression by the lag-screw principle is also renewable. The same device is incorporated in the external construct, to hold the articular fragments reduced to the rest of the bone. The articular screws need not be in the same sagittal plane as shown in the drawing, and can be creatively inter-connected to other construct components]

BRIEF DESCRIPTION OF DRAWINGS

FIG 1 is a diagrammatic front elevation of the improved external fixation implant with lag screw capability.

FIG 2 is a cross section of the improved basic external fixation implant in bone, showing radial pre-stress.

FIG 3 is a front elevation of the improved basic external fixation implant driven in a single bone fragment, exerting radial pre-load, surface pre-load, and axial pre-load widely distributed over bone implant interfaces. No lag screw capability is intended.

FIG 4 is a prior art two-piece internal fixation device applied to two fragments of a fractured femur, with sliding capability of screw within the plate barrel, in a coronal plane view.

FIG 5 is a prior art external fixator attempting to hold two fragments of a fractured femur, in a coronal plane view.

FIG 6 is a coronal plane view of the two piece fracture of the femur, showing the improved lag screw compression device across the fracture into both fragments, and the

improved basic external fixation implants holding the distal fragment only; all taking part in the external fixation construct through connecting clamps.

FIG 7 is a five piece fracture of the distal femur with five fracture interfaces, in which the improved basic external fixation implants are holding only one large proximal fragment; and five improved lag screw external fixation implants are holding all the five fragments as well as compressing the five fracture interfaces, all being parts of the external fixator construct with tubes and clamps.

new matter

FIG 8 shows a prior art device with flat base, of Taylor et al, in which by driving at near a right angle to the fracture surfaces, the device becomes inclined to the outer bone surface at about 45 degrees, with engagement on edge.

new matter

FIG 9 shows the improved invention external fixation lag screw, inserted at about right angles to fracture plane, and at about 45 degrees to the outer bone surface, with the spherical head making a concentric and broad contact and distributing load in the matching countersink in bone surface.

new matter

FIG 10 Is an oblique basal view showing magnification of the hollow dome shaped head and adjoining portions towards the ends, of the improved basic implant.

FIG 11 is an oblique basal view showing magnification of the hollow conical head and adjoining rod towards both ends, of the improved basic implant.

FIG 12 is an axial section of bone from which the improved basic external fixation implant has been removed, leaving behind a protective ridge of bone around the drill hole.

[DETAILED DESCRIPTION OF THE INVENTION]

[The invention distinguishes itself from older internal fixation screws in lag mode by the following qualities.]

[The conventional lag screw is imbedded in the tissues after the wound is closed over it, whereas the invention projects outside the skin surface.]

[The conventional screw in lag-screw mode cannot be accessed repeatedly for refreshing the compression between fragments. This would require repeated anaesthesia and reopening of the wound. The invention being outside the skin can be loosened in the clamp, turned tighter on the bone, and secured again to the clamp.]

[The invention distinguishes itself from the conventional basic implant of the external fixator in the following features.]

[The conventional implant can be inserted with a radial preload to enhance its stability, by driving it through a suitably smaller drill-hole. The radial preload can be applied in this invention also. However, in addition to this radial preload, the principle incorporated in its design adds two other stabilizing factors. One is an axial preload along the thread. The other is the surface preload of the head on the bone surface, which works at an angle of 90 degrees to the radial preload. These three combined effects gives the] [invention better immediate and more durable stability without loosening.]

[The conventional Schanz screw implant once loosened, stays loose and encourages sepsis. Due to the presence of the intercalated head in the invention, it is [possible to renew its stability by turning it tighter, periodically. Stability of implant discourages sepsis. Though the radial preload is not renewable, when supplemented by the other two preloads, it lasts longer. Even if radial preload is abolished with time, the

other two are renewable.]

[The conventional Schanz screw was never intended for the lag-screw mode. It was primarily for getting control over the main two fragments of bone in a fracture by engaging them. After this the fragments could be manipulated into reduction by moving] [the fragments about with the leverage gained, and fixed. If ever inserted across a fracture line, it could only splint the fragments across, with or without gap. Passive sliding is prevented by the fixator clamps.]

[The claimed invention is not only capable of being inserted in the lag-screw mode, but has the unique quality of allowing renewal of the compression from out-side. This is in addition to its function as a basic implant.]

[The tip of the screw is self-tapping where the torque required is not excessive. In hard bone , more lasting stability is gained by using a bone-tap prior to screw insertion. Short threaded screws in lag mode, and those which may need removal and replacement, are not self-tapping.]

[The canulated pattern can be very helpful for intra-articular fragments, by allowing a guide-wire technique.]

[The length of the thread is short when intended for the lag-screw mode. The thread can then be kept out of the fracture line at the end of tightening.]

[For the basic implant mode, the screw is fully threaded, to encourage broader contact area for axial preload on the thread.]

[For fixation of intra-articular comminution, a fully threaded screw is chosen to prevent the articular surface from getting narrowed.]

[The ratio between the outer diameter of the screw and the core diameter is generally larger in cancellous bone than in cortical bone. The pitch of the thread is higher for cortical bone.]

[If the partially threaded device is used, the smooth screw-shaft is of sufficient] [length and proper diameter to clear the gliding hole in the near fragment.]

[If intended as a renewable compression lag-screw, the thread length selected will be such that the thread does not cross the fracture line, at the end of tightening.]

[The presence of a shaft from the thread to the head is only for gliding of the screw in the near fragment; for compression without catching in that fragment, in the lag-screw mode. Radial preload is still applicable.]

[The most functional part of the invention is the intercalated screw-head, its shape and position, which adds to the meaning and alters the functions of other components of the device.]

[The head, which is intercalated between the inner and outer tips of the device may be fixed to the rod , or may be mobile. It may be hemispherical on the deeper side like a conventional screw-head, spherical, or discoid or any other shape that may suit its] [purpose of exerting the intended pressure on the bone surface. The discoid head may have a blunt serrated deeper surface to exert limited contact. There may be an in-built washer under the head, which distributes pressure over a wider area over bone surface.]

[The external drive-shaft is an extension of the inner screw, to give it the simultaneous functions of participation in an external construct, and of renewing

the compression torque.]

[The outer grip end can be, by the preference of the user, either milled or quick coupling or triangulated.]

[The overall size of the device can be made to suit the size of the bone, the size] [of fragments being dealt with, and the depth of the bone from skin.]

[The device being an implant shall be manufactured out of an inert implantable material, having other suitable physical attributes.]

New matter before was "Tapping"

DETAILED DESCRIPTION OF THE INVENTION

FIG 1 is one form of the improved lag screw implant. It comprises

1, being the tip with self- cutting capability at the first end/ Such a tip removes the need for using a bone tap for cutting the thread, and is expedient. New Matter.

2, is the short- threaded section at the first end.

3, being the smooth screw shaft section has no chance of catching either in the wall or the edge of the drill hole. This is to disallow any chance of friction, which may occur while attempting to lag by over- drilling a gliding hole, and then to expect a fully threaded screw to glide through it smoothly. New Matter

4, is the spherical head for engaging the outer fragment of bone, which is capable of exerting well distributed pressure in a matching countersunk area at the outer surface of bone. This pressure will be even and equally distributed no matter what the improved device subtends at the bone surface. The head may be integral with the rod as in the drawing, or may be mobile to slide along the rod, to be fixed in a desired position by means of a transverse screw in the head, which can be driven into one of a series of holes New Matter New matter

provided in the rod.

new matter

The head 4 co acts with the thread 2 to tension the implant and compress a sliding fragment onto a fragment in which the thread is engaged for turning.

5, is the unthreaded drive shaft, which serves for driving the device, as well as for being secured through a connecting clamp to the external fixation construct. It also serves for renewing any compression lost subsequently over time. Such a loss of torque can occur due to head engaging some soft tissue covering the bone surface; this tissue will undergo necrosis under pressure and melt away in some time. It can be due to absorption of the fracture surfaces, etc. The improved device can be momentarily loosened at the clamp, turned tighter, and secured again at the clamp. The head 4 will continue to sit snugly at the countersink.

new matter

6 is the second end, with the gripping means at the second end, shown as a milled surface in this drawing, but the same can be quick coupling, or faceted, to suit the gripping handle or chuck.

new matter

7, is the guide-wire passing through the central canal running lengthwise in the entire device, from first end 1 to the second end 6. Since a lag screw is most effective at about right angles to the fracture surface, direction is most important. The guide wire helps to find the optimum direction, without damage to the bone stock which will occur if the bulkier implant itself is used to make repeated drives in bone.

new matter

The lag screw is mainly effective in tension mode, along the axis of the screw. Other forces of gravity and muscle pull are to be neutralized by the main external construct. Due to this consideration, it is possible to overlook the fact that a lag screw driven with a

new matter

self-cutting tip is somewhat less durable than a screw with a non-tapping tip driven after cutting the thread with a tap.

new matter

FIG 2 shows the cross-section 11 of a prior art Schanz screw half pin, driven into a drill hole of a slightly smaller diameter creating a radial pre-load 8, which is within the tolerance of the bone tissue. A higher load will lead to micro-fractures in the walls of the drill-hole, with crumbling of bone and loosening of device. The same technique is also applicable to the improved implant, being beneficial to stability. The surrounding bone tissue is designated B.

new matter

before was prior art.

FIG 3 shows one form of the improved basic external fixation implant, inserted in tubular bone B.

1 is the non-self cutting tip at the first end. It is driven only after a thread has been cut with a bone tap, which is in the interest of durability, since the implant has to withstand significant forces of muscle pull and gravity.

new matter

2 is the threaded portion from tip 1 to the intercalated head 4. The full thread ensures maximum interface area with the female thread in bone, to tension the imbedded portion of implant, generating the axial pre-load 10.

Radial pre-load 8 has already been created by prior art technique, of driving the device through a judiciously smaller diameter drill hole. Too small a drill hole will overload the walls of the hole with damage to bone structure and loosening of the implant.

4 is the truncated conical hollow head, apex towards the second end 6. It makes contact with bone surface of a single fragment B, through blunt podia 14, created by a wavy or beaded margin of the rim of head base.

The gaps between the podia allow surface blood supply and nutrition to reach the margins of the drill hole, and encourage a ridge of new bone to form around the drill hole.

This ridge is similar to that which forms around the sides of a bone plate, and strengthens the bone at the time of implant removal.

The podia exert a surface pre-load 9 on bone surface, and co acting with the thread, tension the implant axially.

Lateral forces applied to the drive shaft 5 are transmitted through the hollow head 4 through the podia 14 to the outer surface of bone and largely bypass the drill hole/ implant interface.

The head of the improved basic implant being integral with the rod, there is no micro-movement between the implant components, transmitting cyclic stresses to the implant/bone interfaces.

new matter

For a superficial bone like the tibia, an improved basic implant with a squat hollow head is selected, which will find ready skin cover. For deeper bones like the femur, a longer conical hollow head will be found easier to extract, at the end of treatment.

All stress applied to the second end of implant are widely distributed at the surface, drill hole and thread interfaces.

The engagement surface 14 of head is in a plane at right angles to the long axis of the improved device, because it is mechanically most efficient to drive the basic device at right angles to the bone surface. The engagement plane then fully meets the bone surface with broad contact.

Since it is easy to direct a drill at right angles to bone surface, there is no need for a guide

new matter

wire technique. This works out in favor of the required strength of a basic external fixator implant, by eliminating the need for a lengthwise central canal in the rod.

FIG 4 is a coronal view of femur with fracture F, giving rise to two bone fragments B and B'. A prior art two-piece internal fixation device, a sliding hip screw, is holding the fracture reduced at F. X is the hip screw and Y is the barrel of the plate in which the screw slides out in case of absorption of fracture surfaces and shortening of bone.

The device can also be tensioned by means of a small screw Z in the outer end of the hip screw X, engaging the outer end of the barrel Y by means of a head. new matter

new matter The compression can soon wear off, with no possibility of renewal. Sliding of screw within barrel may fail due to jamming, because forces in the area are not along the axis XYZ to encourage such an event. S is the skin integument of the part.

FIG 5 is the same fracture of FIG 4 held with one type of prior art external fixator, using prior art Schanz screws P, secured to an external tube strut 13, by means of a series of clamps 12. Absence of any head engaging the fragment B' precludes lag screw compression of B and B'. Gap may already be present at the fracture site at the end of surgery, or may occur later, which is adverse to bone healing.

FIG 6 is the same fracture of FIG 4 and 5, treated with the claimed improved implants. The upper two are improved lag screw implants, compressing fragments B' and B, across the fracture F, at nearly right angles to the fracture plane.

The lower two are improved basic implants into a single fragment B', gripping the fragment more securely with wide stress distribution at implant/bone interfaces.

Clamps 12, to tube 13, connect all components.

new matter

In the event of loss of lag screw compression, the lag screws can be loosened one by one at the clamp, turned tighter, and secured again at the clamp.

Just in case there is loss of stability of the basic implant, the same also can be restored by similar subsequent tightening.

Radial pre-load once lost is not renewable, but due to the improved design, the surface and axial pre-loads are renewable. The latter two also do protect the radial pre-load, in the case of the improved basic implant.

Renewed and sustained compression of fracture surfaces, aided by a stable basic construct, lead to quick union and reduce the chances of loosening, infection, and failure to unite. Numbers 1 to 6 are implant parts as per FIG 1.

FIG 7 shows a femur with multiple fractures in its distal end, with two epiphyseal fragments B'' and B''' bearing joint surfaces, and three more fragments B, B' and B'''' extending from metaphysis to diaphysis of bone.

Two improved basic external fixator implants hold the upper large diaphyseal fragment B.

The lower five are improved lag screws, of which the lowest two are lagging the joint fragments B'' and B''' into compression, at nearly right angles to the fracture plane F''. The third lag screw from below lags three fragments B'''', B' and B'', across fracture lines F''' and F'.

Since these two adjoining fracture planes cannot be parallel, the device cannot be at right angles to both of them. Due to this the best angle of insertion is to be decided by the experience of the surgeon. While in this drawing the device seems nearly at right angles

to the surface of the bone, most lag screws end up at various angles of inclination to the outer surface, in order to be at right angles to the fracture plane.

new matter

The fourth and the fifth improved lag screws from below are nearly at right angles to the fracture planes F'''' and F, with spherical heads lodging in matching countersunk beds in bone surfaces of fragments B'''' and B, with wide contact.

The drawing is diagrammatic, in which all implants are shown in the same coronal plane. In practice, the construct can be made more creative in different planes, to accommodate the needs of the fracture and soft tissues.

new matter

FIG 8 is one type of prior art implant of Taylor et al. When inserted at right angles to the fracture plane F in bone fragments B and B', the device is at about 45 degrees to the outer bone surface. This has caused the engagement means 4 to stand on edge at 45 degrees to the bone surface. The engagement means of all the implants patented by Taylor et al have an engagement plane at right angles to the rod axis, which will give consistent incongruous engagement problems in actual use.

new matter

FIG 9 shows the claimed improved external fixator lag screw with spherical head 4 nesting snugly with wide concentric stress distribution in a matching countersunk area C in bone surface of fragment B.

new matter

At any other angle of insertion also, the head will have the same concentric load distribution, preventing crumbling of bone due to stress concentration.

FIG 10 is an oblique basal view of the hollow dome shaped head 4 with podia 14 formed by a wavy margin of the rim of the base, for making interrupted contact with bone surface.

2, is the fully threaded section from first end 1 to the head 4.

FIG 11 shows a conical hollow head with blunt beaded podia at the margin, for interrupted contact with bone surface.

Interrupted contact allows surface blood vessels and nutrition to reach under the head to the drill hole margins, which maintains the bone integrity and encourages a rim of new bone formation, in the manner of such new bone forming at the margins of a bone plate.

new matter

FIG 12 is a section of bone across a drill hole left after removal of the improved basic external fixator device.

A rim of new bone is seen in the section around the drill hole D at the margin, to strengthen the bone at that weakness left by implant removal. This is due to the novel head design allowing nutrition of the drill hole margin, the surface cortex under the hollow head, and the outer third of the bone cortex in that small area.

A similar ridge of bone around a bone plate is not removed at the time of plate extraction, to retain the strength of bone by means of this natural phenomenon.

[CLAIMS]

[What I claim as my invention is:]

[An implantable screw-like device, which can serve simultaneously the following Functions or capabilities.]

1. [Acting as an improved basic external fixator implant with triple stabilizing factors of radial preload around the drill-hole of a smaller diameter, axial preload on the thread along the length of the drill-hole, and surface preload of the head upon the bone surface at 90° to the radial preload.]

2. [Capable of renewing the enhanced stability by subsequent turning of the device.]

3. [Acting simultaneously in an internal lag-screw mode, and participating in an external fixator construct.]

4. [Capable of repeated renewable lag-screw compression from outside the skin, since] [this compression always gets loosened with time in the conventional implanted lag-screw, without any need for repeat anaesthesias or re-exposures to search for screw-heads.]

5. [Adding the renewability of compression, to cannulated screws in lag mode, inserted with guide-wire technique into joint fragments.]

6. [The claim is for the principles stated above and not for any single particular pattern or dimensions thereof. I claim any device capable of the above functions, made of whatever material, whether for human or veterinary or any other implantation or mechanical application, as my invention.]

7. [While originally being intended to the above purposes, I further claim the] [invention even if it is used for other biological fixations/immobilizations such as botanical or other forms of life, and in tissues other than bone wherever applicable].

8. [I further claim this invention in connection with any other use as in engineering or any other field of mechanical or biological endeavor, in which it serves to hold and compress together two or more fragments or masses of material together, while taking part in an outside construct.]

<u>CLAIMS</u>

<u>13. an improved solid rod like basic half-pin implant for external fixator systems, intended for being driven at right angles to bone surface; comprising,</u>

<u>a first end, with a thread at said first end; and a second end, with a means for gripping;</u>

<u>an intercalated hollow dome shaped head with an open base or equatorial area, with convexity or apex away from the said first end, having a blunt rim at base for contact with bone surface, the contact being interrupted by the presence of a blunt wavy margin of the rim, the said head being integral to said rod to disallow any micro-movement between said rod and said head;</u>

<u>the device being fully threaded from said first end to said head; and</u>

<u>the device having an extended rod length towards said second end beyond the said head as a means of driving the device, and also for securing it to an external fixator construct.</u>

<u>14. The device of claim 13 in which the said head is hollow conical, with apex</u>

towards the said second end, with an open base and a blunt rim with wävy margin for load on bone surface.

15. The device of claim 13 in which the said basal rim is blunt beaded, instead of wavy.

16. The device of claim 14, in which the said basal rim is blunt beaded, instead of wavy.

17. The device of claim 13 in which the threaded portion is hydroxyapatite coated.

18. The device of claim 14 in which the threaded portion is hydroxyapatite coated.

19. The device of claim 15 in which the threaded portion is hydroxyapatite coated.

20. The device of claim 16 in whcih the threaded portion is hydroxyapatite coated.

21. The device of claim 13 in which:

the said intercalated head is spherical for a concentric and broad contact with a matching countersunk bone surface, at whichever angle the device subtends with the said surface; also being capable of being seated concentrically on a washer with a matching excavation on the head side face of the washer, at any angle subtended by said device; and

the thread at said first end being short, leaving a smooth screw shaft between said thread and said head.

22. The device of claim 21 being canalized throughout, from said first end to said second end, to allow a guide wire to be passed from said first end to said second end, and from said second end to said first end.

23. The device of claim 21 with an intercalated spherical head, which can be shifted up and down the said device and fixed to the said shaft by means of a transverse screw in the said head being driven into a hole in the said shaft, such holes having been provided at intervals along the said shaft.

24. The device of claim 22 in which the said head is capable of being shifted and fixed in a desired position along the said shaft by means of a transverse screw in head being driven into one of the serial holes provided in the said shaft.

[ABSTRACT OF THE DISCLOSURE]

[The claimed invention called the "Renew Compression Screw" pertains to a rod-like screw device with a thread at the deep end, an intercalated screw-head between the thread and its outer end for participation in a construct, primarily intended for use as an external fixator bone implant. It serves as an improved primary bone implant with triple stabilizing factors instead of only a radial preload. It also serves as a compression screw in lag-screw mode. These two combined functions in themselves are unique, to which is added the capability of renewable stability in basic mode, and renewable compression by lag screw mode. Such a combination of functions has not yet been described in any device.]

ABSTRACT

An improved half-pin lag screw implant for external fixator constructs in which two or more bone fragments can be compressed together by lag screw principle, in which the implant can be driven at right angles to the fracture surfaces with or without a guide wire technique, to yield maximum mechanical compression at right angles to the fracture plane, in which the implant can be driven at any required angle to the outer bone surface other than a right angle, with an intercalated spherical head for that purpose which will exert concentric pressure over a matching countersunk area in the bone surface, thus preventing micro-fractures of bone surface and loosening, brought about by localization of stress on bone beyond its mechanical tolerance. The same implant exerting lag screw effect by means of a thread at the leading tip engaging only a single bone fragment near its tip, and a smooth shaft section extending to the intercalated spherical head, which

allows the second and any intervening fragments to slide over the smooth shaft, with the head pressing on the outermost fragment, as the device is turned home. The outer end serves as a drive shaft for turning the screw, as well as for participation in an external fixator construct through connecting clamps, and also for renewal of any compression torque lost over time. Also an improved Basic external fixation implant for gripping a single bone fragment with a hollow conical or dome shaped head with an open base, with apex or convexity towards the outer end of the implant, a blunt rim of the hollow head resting upon the bone surface, making interrupted contact by a margin that is undulated or beaded, which allows nutrition to reach under the hollow head to generate a ring of new bone at the margin of the drill hole, to reinforce the strength of the bone on removal of implant. Triple stabilizing factors being a radial pre-load by driving implant through a smaller drill hole, a surface pre-load of head which transmits lateral bending stresses from drive shaft through head to the surface of bone instead of to the drill hole margins, and an axial pre-load tensioning the implant against the female thread in bone. The triple mechanism distributes stresses widely at three implant/bone interfaces to reduce tendency for loosening at drill hole/ shaft interface. The surface and axial pre-loads are renewable by further subsequent turning in. The basic implant being fully threaded from leading tip to intercalated head, avails of maximum contact with bone thread for wide stress distribution; and the head being integral to rod, rules out any cyclic micro motion between implant components. In the interest of implant strength, the basic implant is of a solid cross-section. In the interest of ideal angle to the fracture plane, the lag screw implant of canalized variety allows a guide wire technique. The lag screw implant also

has the option of a mobile head, which is fixable to rod at desired level, to reduce inventory.

Pathak

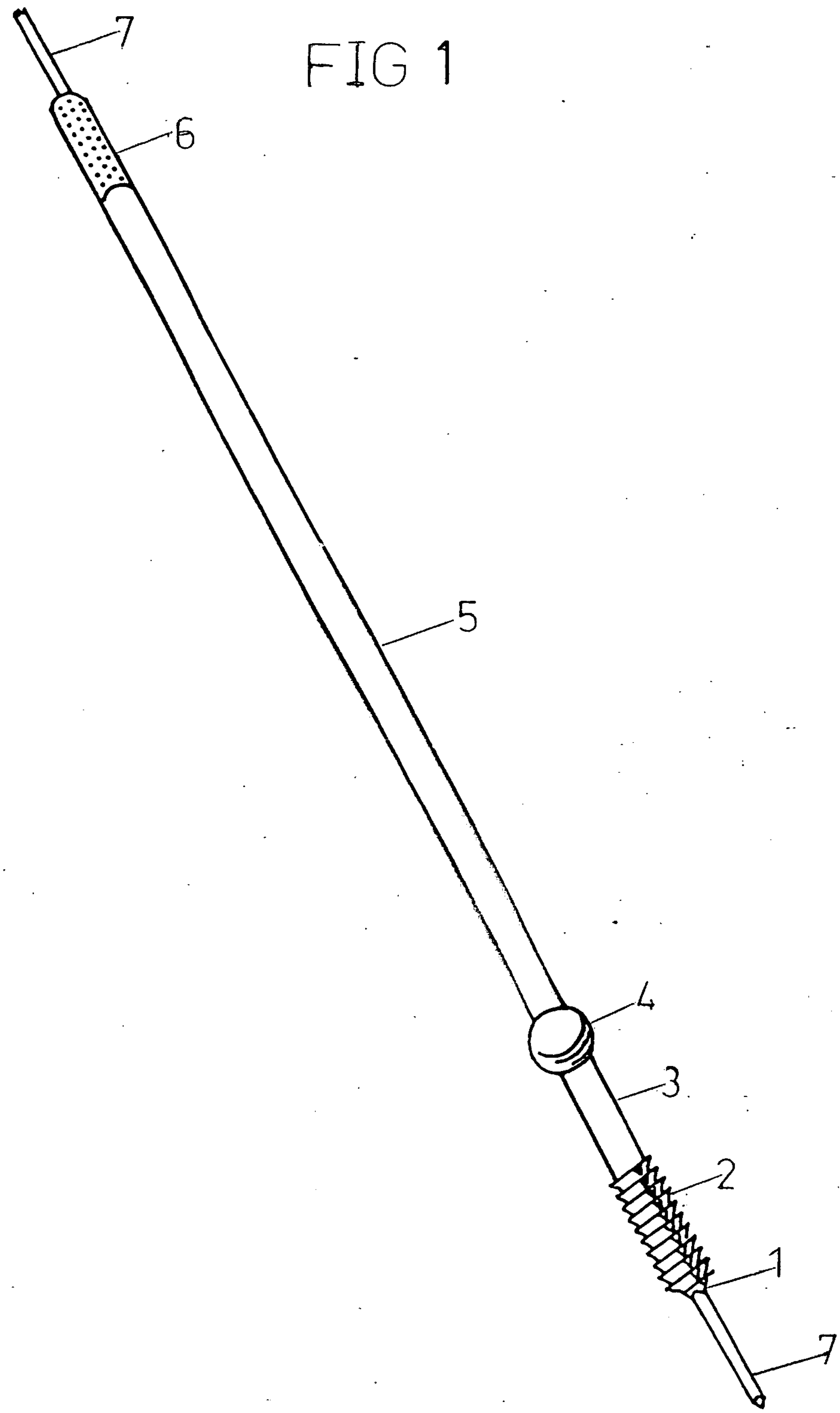
(K. P. PATHAK)

Place : Ahmedabad, India.

Date : ~~July 16, 2000.~~ February 10, 2002.

Dr.Kartikeya P. Pathak.

FIG 1



Entry approved EAV 11/29/03

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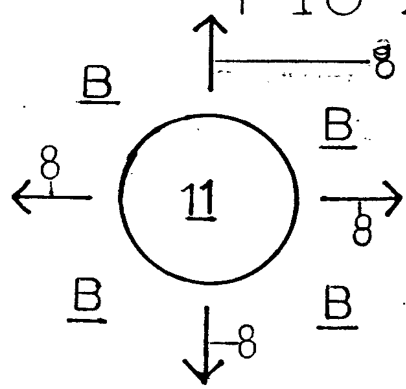
FIG 2.

PRIOR ART.



B.

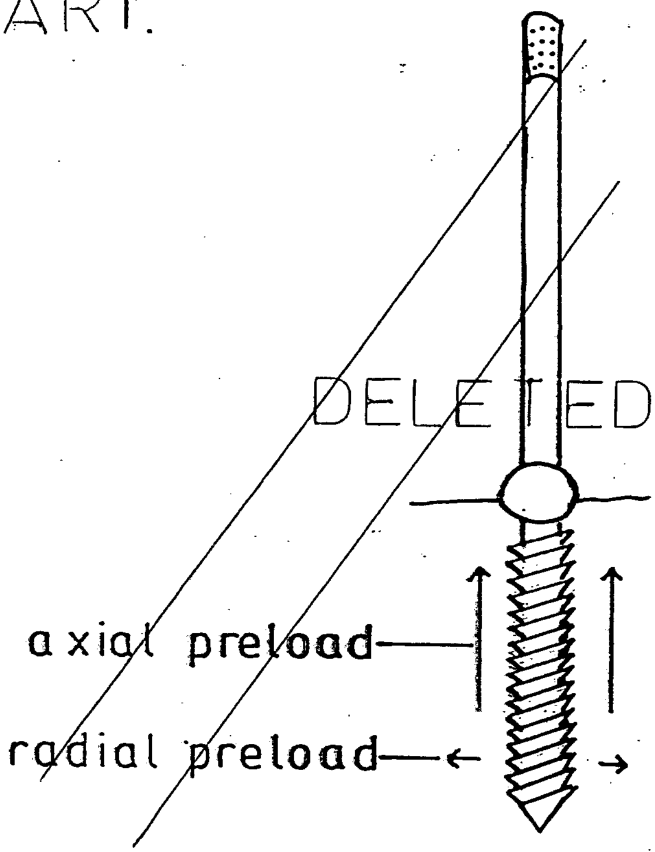
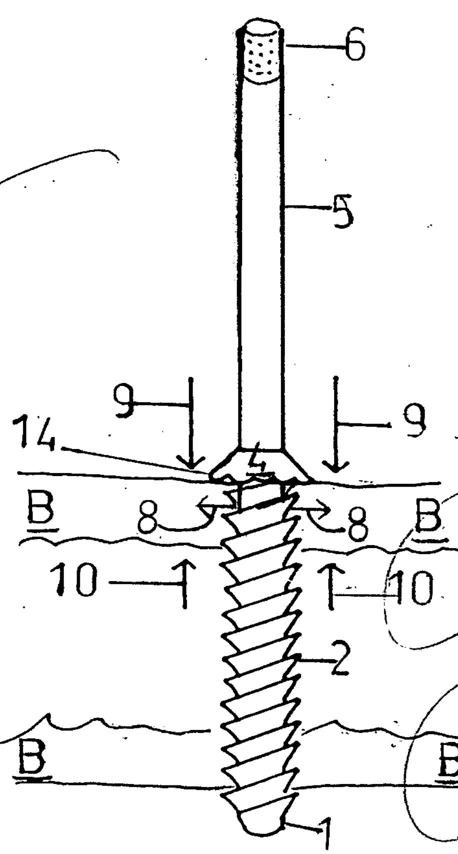


FIG 3.



new matter

new

new

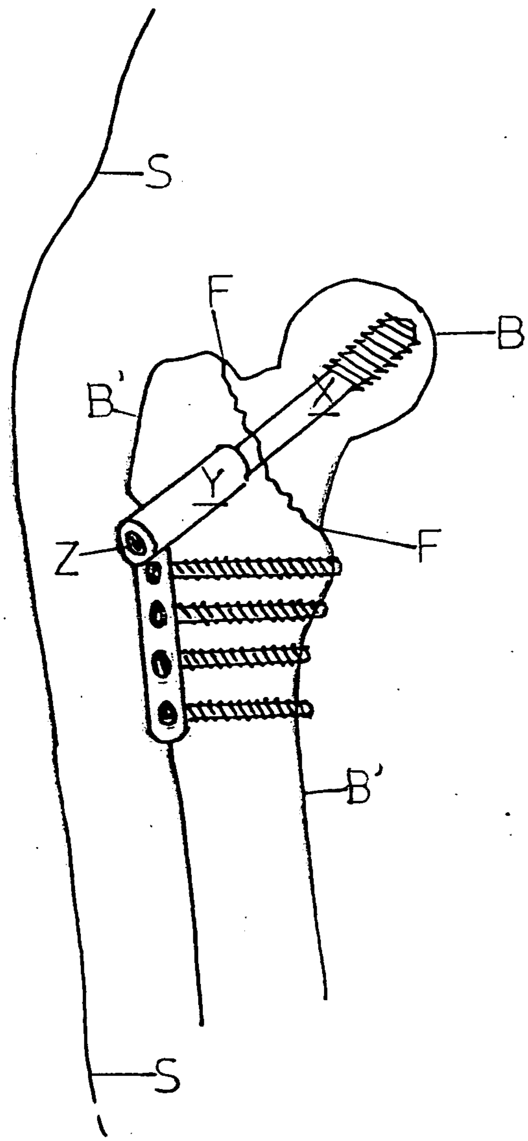
* the figure is new not presented befor

That was ~~not before~~

It appear like before was innovat.

Dr. Kartikeya P. Pathak.

FIG 4. PRIOR ART



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PRIOR ART.

FIG. 5

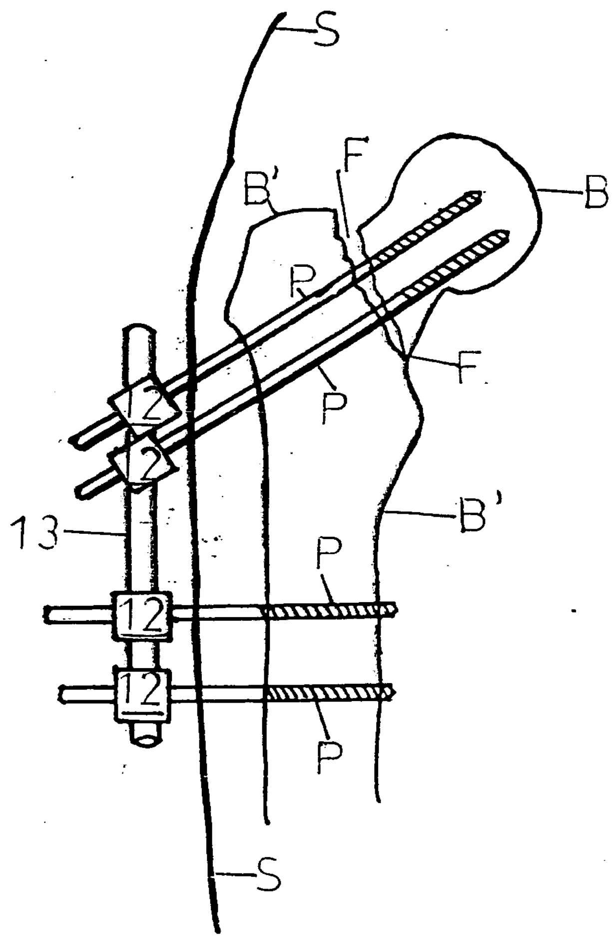

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FIG. 6

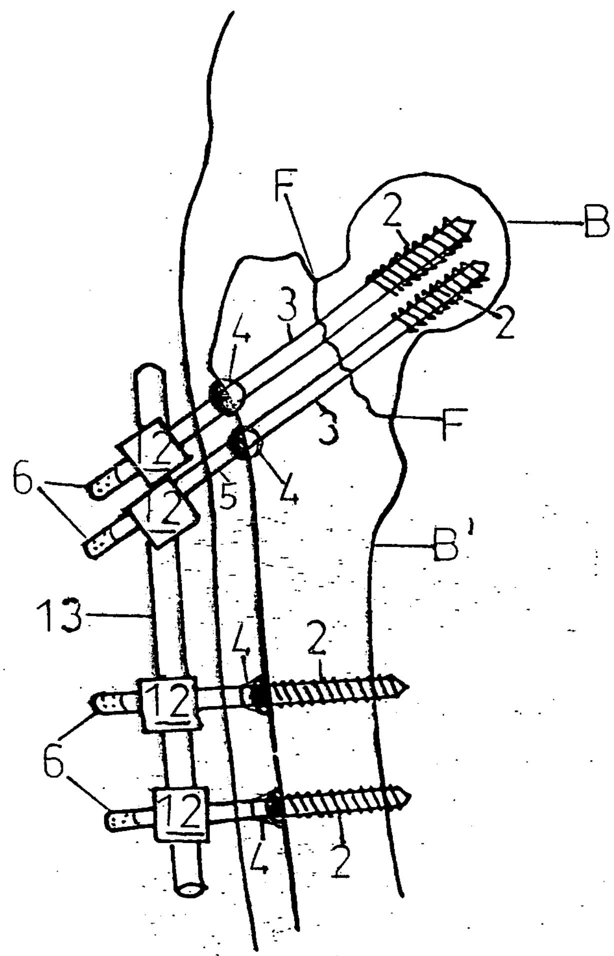

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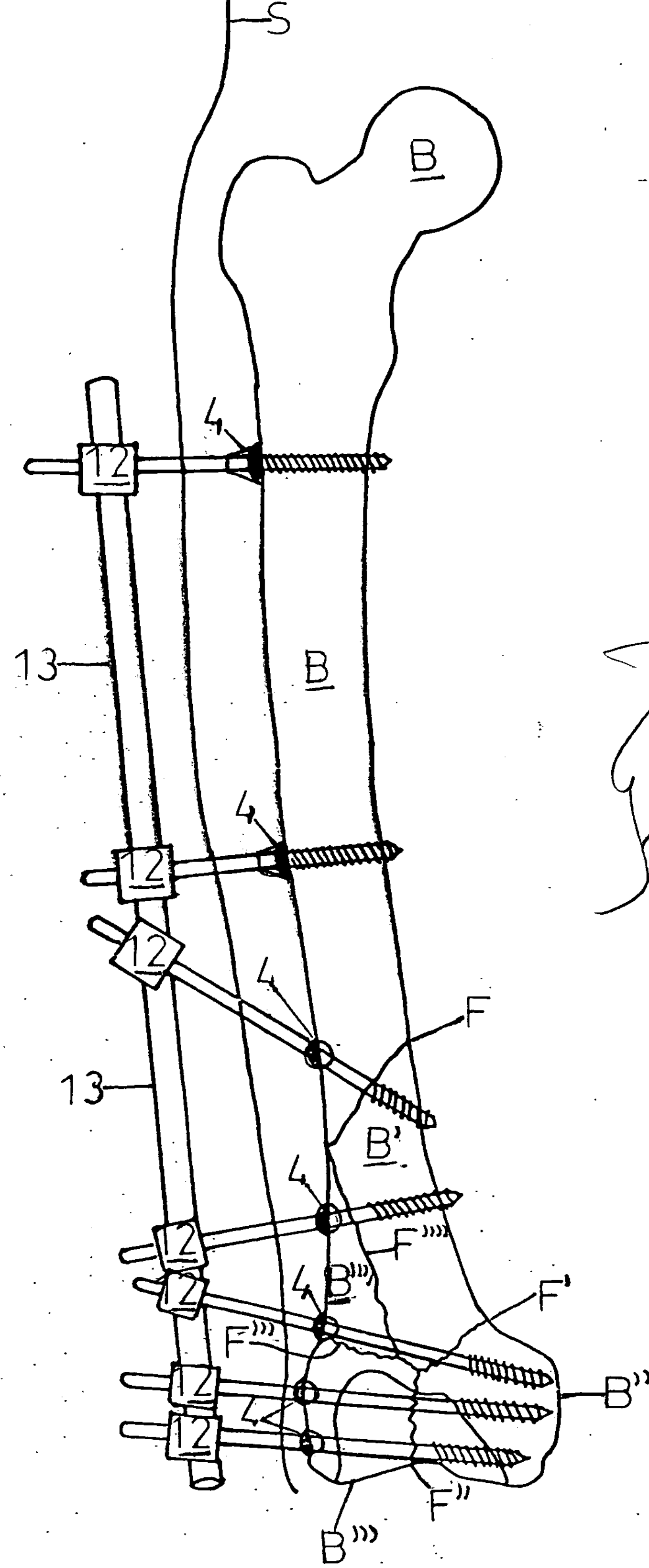
FIG. 7



new matter

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PRIOR ART

FIG. 8

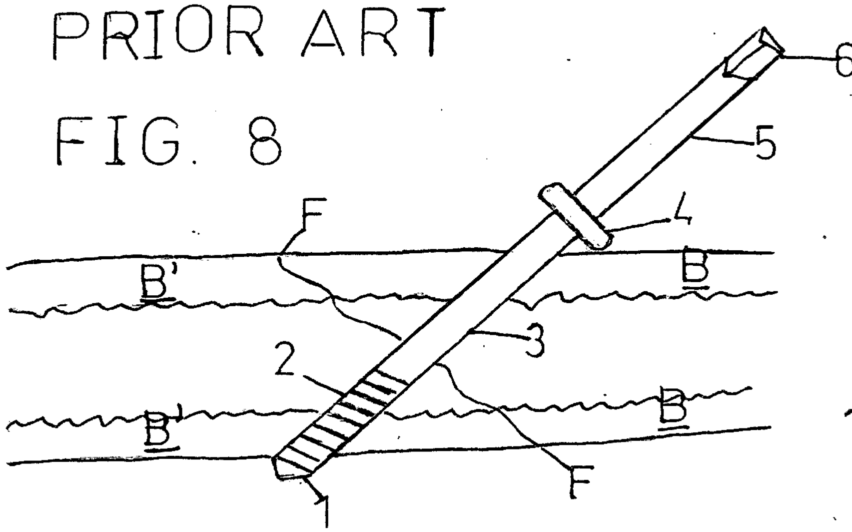

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FIG. 9

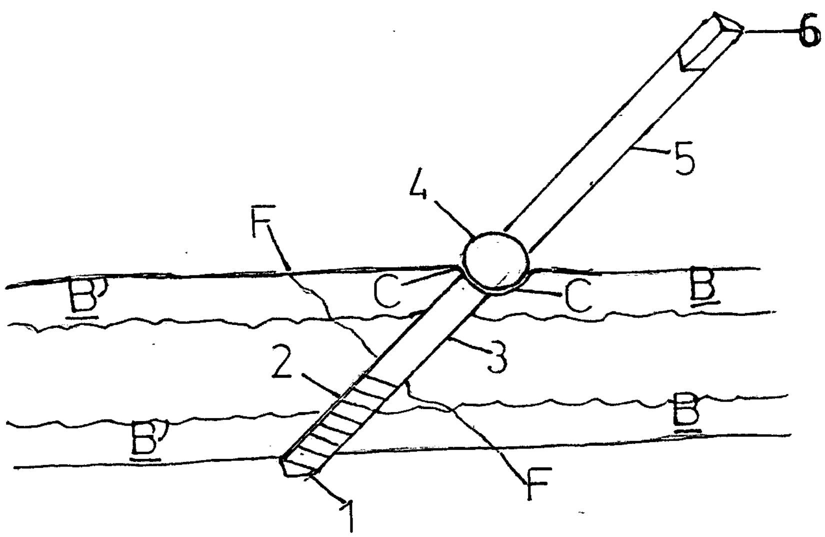

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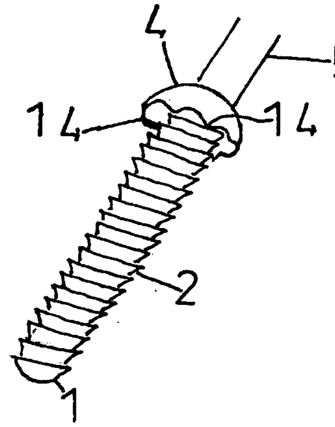
FIG 10



new matter

FIG. 11

new matter

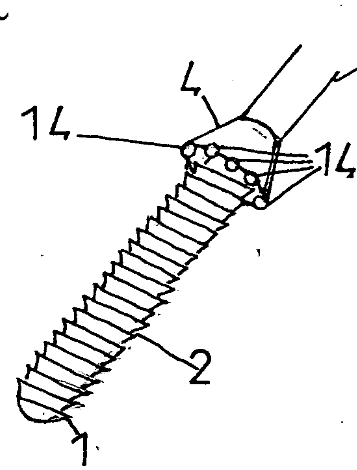


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FIG. 12.